UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 2005-0796

Ex parte Lei YU
(09/626,616)

Before WILLIAM F. SMITH, TORCZON, and GRIMES, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

INTRODUCTION

Yu seeks relief (AP.B, 11/07/2003 [Br.]) under 35 U.S.C. 134(a) from the final rejection of claims 86-90, 92-99, and 101. We reverse on the two bases for rejection.

FINDINGS OF FACT

The following enumerated findings are supported by at least a preponderance of the evidence. For each rejection, the examiner bears the ultimate burden of proof on the question of patentability. In re Caveney, 761 F.2d 671, 673, 226 USPQ 1, 3 (Fed. Cir. 1985).

[1] All appealed claims stand rejected under 35 U.S.C. 112(1) for lack of written description.

[2] All appealed claims stand rejected under § 112(1) for lack of enablement.

[3] The examiner has withdrawn a third rejection under 35 U.S.C. 112(2) (APEA, 01/14/2004 [Ans.]).

[4] Yu states that the allowed and objected claims do not stand or fall with the rejected claims (Br.3).

[5] Yu does not specifically argue the patentability of any claim other than claim 86.

[6] Claim 86 is one of two independent rejected claims (Br.12-14).

[7] Claim 86 defines the invention as follows (Br.12):

> A process for screening a candidate substance for its ability to bind a mu opioid receptor comprising:
>
> (a) providing a recombinant opioid receptor polypeptide encoded by a nucleic acid sequence comprising at least 35 contiguous nucleotides of SEQ ID NO:7, including the guanine nucleotide at position 389 of SEQ ID NO:7;
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> (b) contacting the candidate substance with the recombinant opioid receptor polypeptide; and
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> (c) detecting the ability of the candidate substance to bind to the recombinant opioid receptor polypeptide.

[8] Yu points to the following passages from the specification for written support of the claimed subject matter (Paper 1 at 10:12-20, 12:3-15, and 17:12-23, respectively, underlining in original):

> In one aspect, the present invention provides isolated and purified polynucleotides that encode a mu opioid receptor polypeptide[,] a transcription regulatory polypeptide and/or opioid receptor[-]like polypeptides. In a preferred embodiment, a polynucleotide of the present invention is a DNA molecule. Even more preferred, a polynucleotide of the present invention encodes a polypeptide comprising the amino acid residue sequence of SEQ ID NO: 2 or SEQ ID NO: 4, SEQ ID NO: 8 or SEQ ID NO: 17. Most preferably, an isolated and purified polynucleotide of the invention comprises the nucleotide base sequence of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 7 or SEQ ID NO: 16.
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> * * * * *
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> The present invention also encompasses an isolated and purified polynucleotide that comprises a base sequence that is identical or complementary to a segment of at least 10 contiguous bases of SEQ ID NO: 7, wherein the polynucleotide of the invention hybridizes to SEQ ID

> NO: 7, or a complement of SEQ ID NO: 7. Of course, polynucleotide segments of 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100, 125, 150 or more contiguous bases are also expected to be of use in the invention. Preferably, the polynucleotide comprises a base sequence that is identical or complementary to a segment of at least 25 to 70 contiguous bases of SEQ ID NO: 7. For example, the polynucleotide can comprise a segment of bases identical or complementary to 40 to 55 contiguous bases of SEQ ID NO: 7. In certain preferred embodiments, the claimed polynucleotide will include nucleotide number 150 of SEQ ID NO: 7.
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> * * * * *
>
> In yet another aspect, the present invention contemplates a process of screening substances for their ability to interact with a a [sic] polypeptide of the invention comprising the steps of providing a polypeptide, obtaining a candidate substance, and testing the ability of selected substances to interact with the opioid receptor polypeptide. The interaction measured can be inter alia: the ability of the receptor to bind the candidate, the binding affinity, the intrinsic activation ability of the candidate activation of ion channels in the cell membrane, modulation of ion channels in the cell membranes, or modulation of cellular biochemical processes. These interactions can be measured by any of a number of means known in the art. By measuring these interactions, those of skill will be able to selectively modulate biochemical processes in the cells by selecting pharmacological compounds with desired characteristics.

[9] The specification does not expressly teach the unique importance of the guanine nucleotide at position 389 in SEQ ID NO: 7.

[10] The examiner, however, indicates (Ans.4) that Example VI (Paper 1 at 121) provides a basis for focusing on this residue in its discussion of the single-base difference with respect to a Wang et al. 1994 article:

> Apart from the length of the claimed polypeptides (35, 45, 50, 75, 100 bases), the only common structural attribute which identifies the members of the claimed genus of nucleic acid molecules and proteins is that they must comprise the guanine at position 389 of SEQ ID NO:7. Example VI, on page 121 of the specification discloses that the [] guanine residue produces a 10-fold increase in affinity in dynorphin A (1-17) binding compared to the protein of Wang et al., which is encoded for by a nucleic

acid molecule which does not comprise a guanine at position 389 of SEQ ID NO:7. However, the general knowledge and level of skill in the art do not supplement the omitted description of what amino acid residues are necessary to produce a functional opioid receptor because specific, not general, guidance is what is needed.

[11] Both of the remaining rejections focus on the broad scope of the claims compared to the level of detail in the specification.

[12] In particular, the rejections focus on the step of providing the polypeptide.

[13] The written-description rejection is based on the high variability of polypeptides that would satisfy the structural limitations, and on the lack of guidance regarding what amino acids are necessary to satisfy the functional limitations of the claim (Ans. 3-4).

[14] The enablement rejection is similarly based on lack of guidance on how to make any receptor other than the one encoded by the complementary deoxyribonucleic acid [cDNA] of SEQ ID NO: 7.

[15] Based on the arguments provided, the specification provides adequate written description of the invention defined by claim 86.

DISCUSSION

Yu has only specifically argued the limitations of claim 86. For the purposes of this decision, claim 86 adequately represents the issues for all of the rejected claims. Hence, the claims stand or fall together based on our analysis for claim 86.[1]

The written-description and enablement requirements of § 112(1) are separate and distinct requirements, although the distinction can be blurry, particularly for

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[1] Claim 94, the other independent claim, is broader to the extent that it is not limited in the preamble to a particular type of opioid receptors, but this difference is not critical to the analysis.

unpredictable arts. University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 921, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004). To satisfy the written-description requirement, a specification need not describe the claimed invention in precisely the same language as the claim as long as one skilled in the art can recognize the claimed subject matter in the disclosure. University of Rochester, 358 F.3d at 923, 69 USPQ2d at 1895. A specification satisfies the enablement requirement if one skilled in the art, after reading the disclosure, would have been able to practice the claimed invention without undue experimentation. In re Wands, 858 F.2d 731, 736-37, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In present case, the examiner expresses concern that the claim is in a sense generic, without adequate specific support. As the quoted portions of the disclosure show, however, there is generic disclosure for a screening method for substances that bind to any polypeptide of the invention. Such polypeptides include those encoded by at least preferably 20-75 nucleotides of SEQ ID NO: 7, with 35 nucleotides being specifically disclosed as a choice. The examiner concedes that the specification teaches the importance of the guanine at position 389 of SEQ ID NO: 7. Hence, all elements of claim 86 are present. We do not understand the examiner to argue that tying these teachings together requires too much undirected picking and choosing. Cf. In re Ruschig, 379 F.2d 990, 996, 154 USPQ 118, 123 (CCPA 1967) (affirming rejection of species claim as not supported by generic description). There is no per se bar to generically disclosed methods commensurate in scope with a generic claim. Consequently, we cannot find on this record that claim 86 lacks written description.

The enablement rejection presents a closer question because, as the examiner observes, the claim is open to a very broad range of polypeptides for use as opioid receptors. We start, however, with the presumption that the specification is enabling. In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). Breadth alone is not a basis for holding a claim to lack enablement.

For the purposes of these claims, the polypeptide has effectively three limitations. First it is structurally limited by being encoded by a minimum range of contiguous nucleotides selected from a specific nucleotide sequence. Second, it is further structurally limited by the requirement that it include a specific nucleotide position. These two limitations admit a large, but deterministic minimum set of nucleic acids that could be generated by a computer program. Since the nucleic acid sequence limitation uses the "comprising" transition, it is open to the inclusion of additional nucleic acids that could encode additional amino acids for the polypeptide. It is not clear from the examiner's argument what part of this would require undue experimentation.

The third polypeptide limitation is functional: it must be an opioid receptor (specifically a mu opioid receptor for claim 86 and its dependent claims). The examiner argues that the specification does not teach how to produce any opioid receptor other than the full-length receptor encoded by SEQ ID NO:7. It is not clear, however, why screening of the recombinant polypeptide for the claimed function would require undue experimentation.

As noted above, breadth alone is not sufficient to justify an enablement rejection. If one of skill were motivated to identify all possible polypeptides meeting the three discussed limitations, the effort involved might be huge because of the huge number of possibilities to rule in or out. The examiner has not, however, provided a basis for finding the experimentation involved to be anything other than routine. PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) (considerable experimentation is permissible if it is merely routine). On the record before us, we cannot find that undue experimentation would be required to make or use the invention of the rejected claims.

DECIDED that the rejection of claims 86-90, 92-99, and 101 for lack of written description be REVERSED; and

FURTHER DECIDED that the rejection of claims 86-90, 92-99, and 101 for lack of enablement be REVERSED.

WILLIAM F. SMITH
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

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cc:

Mark B Wilson, Fulbright & Jaworski LLP, of Austin, Texas, on brief for Yu (Advanced Research and Technology Institute, real party-in-interest).

Robert S Landsman, Art Unit 1647, of Alexandria, Virginia, on brief for the Director of the United States Patent and Trademark Office.